MiraVista DIAGNOSTICS

Rapid Fungal Testing. Accurate Results.

MiraVista *Histoplasma* Urine Antigen Lateral Flow Assay (LFA)

Background

Histoplasmosis is a systemic infection caused by the dimorphic fungus *Histoplasma capsulatum*. Rapid diagnosis is important for early initiation of treatment in progressive disseminated and acute pulmonary histoplasmosis cases. Antigen detection has been proven useful for rapid diagnosis.

Development

We have developed an easy to use immunochromatographic lateral flow assay (LFA) for the visual detection of *Histoplasma* galactomannan antigen in urine.

The MiraVista *Histoplasma* Urine Antigen LFA test can aid in diagnosis of *Histoplasma* infection.

Performance

The MiraVista *Histoplasma* Urine Antigen LFA has a proven clinical sensitivity of 93.18% and 96.97% specificity relative to culture proven cases with a limit of detection (LoD) of 1.8 ng/mL in clinical specimens.

Histoplasma Urine Antigen LFA	Culture	
	Positive (Case)	Negative (Control)
Positive	41	9
Negative	3	288
TOTAL	**44**	**297**

Advantages of the MiraVista Urine Histoplasma Antigen LFA

- **Rapid 3 step process**
- **Quick turnaround time allows for timely diagnosis and treatment**
- **No instrumentation required**
- **Can be performed in low complexity clinical settings**
- **Results are ready in 40 minutes**
- **Non-invasive specimen collection**
- **CE Marked product**
- **No incubation required. Performed at room temperature.**

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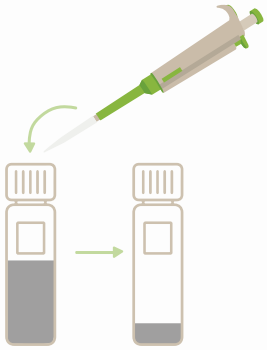
miravistalabs.com/devices

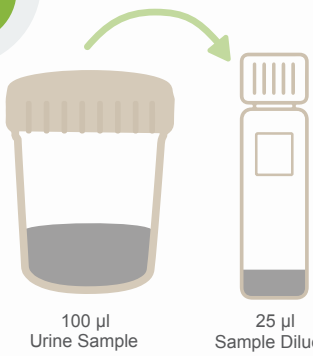
MiraVista *Histoplasma* Urine Antigen Lateral Flow Assay (LFA)

* Prep



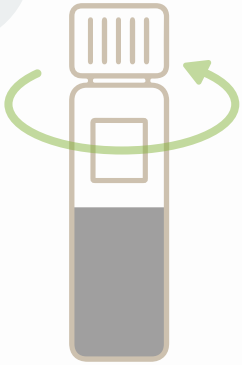
Pipette 25 µl sample diluent into supplied tube.

1 Dilute



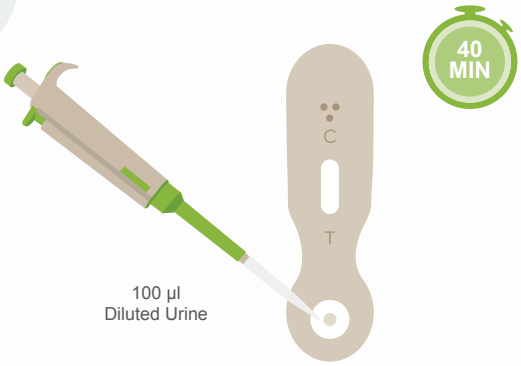
Mix urine sample thoroughly. Pipette 100 µl urine sample into tube with sample diluent.

2 Mix



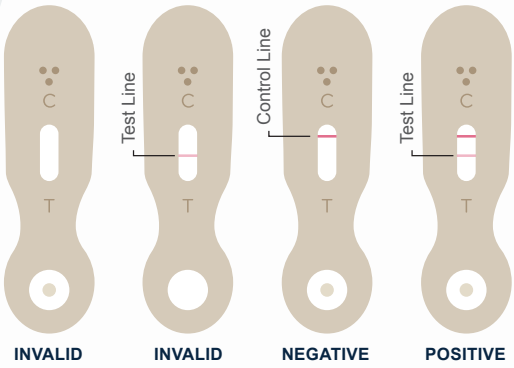
Securely close the tube and mix.

3 Pipette



Lay device on a flat level surface. Pipette 100 µl diluted urine onto the sample pad. Read results after 40 minutes.

* Read



Absence of a control line indicates an INVALID result. Presence of both a test and a control line indicates a POSITIVE result. Absence of a test line and presence of a control line indicates a NEGATIVE result.

FOR REFERENCE ONLY. Refer to Package Insert for Complete Instructions For Use.

MiraVista *Histoplasma* Urine Antigen Lateral Flow Assay is a CE Marked product.
Not FDA cleared. Not available in the U.S.

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